

REMARKS

A. Status of the Claims

Claims 1-31 have been canceled without prejudice to future prosecution. Claims 32-40 are currently pending.

B. Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 32, 33, and 40 under 35 U.S.C. §103(a) as allegedly obvious in view of Katz *et al.* United States Patent No. 5,716,614 ("Katz"). The Examiner asserts that Katz discloses a complex between a biologically active reagent and a transporter held together by van der Waal's and electrostatic interactions. Applicants respectfully disagree.

The Examiner cites column 5, lines 15-17 of Katz, which states: "By complex or conjugate is meant a molecule that is either held together by van der Waal's and electrostatic interactions or by covalent bonds." However, the "complex" referred to by Katz "comprises a biologically active molecule and a residue of an omega-3 fatty acid." See column 5, lines 12-15. Thus, the referenced "van der Waal's and electrostatic interactions" are between the biologically active molecule and a residue of an omega-3 fatty acid, *not* the biologically active molecule and a polylysine.

Katz discloses that the fatty acid complex may *optionally further include* a polylysine. See column 5, lines 36-41. Katz does *not* disclose that the polylysine may be non-covalently bound to the fatty acid complex. In fact, Katz specifically discloses that *the biologically active agent should be covalently attached to the polylysine* to mask activity until the agent is cleaved from the polylysine carrier. See column 6, lines 20-34, stating in part:

One component of the complex is the active agent which is the entity that initiates the therapeutic or physiological response. *It is attached to the carrier* and is *active only after being cleaved* from the vehicle. The attachment of the agent can be to the main chain of the poly-L-lysine carrier" (emphasis added).

Therefore, Katz fails to teach or suggest a polylysine carrier that is non-covalently attached to a biologically active agent. Moreover, Katz explicitly teaches against non-covalently attaching a biologically active agent to a polylysine in order to mask activity until cleavage from the polylysine carrier.

Because Katz fails to teach or suggest a polylysine carrier that is non-covalently attached to a biologically active agent, Applicants respectfully request withdrawal of the rejection.

B. Double Patenting Rejection

The Examiner has rejected claims 32 and 40 as allegedly obvious in view of claims 1, 6, and 7 of U.S. Patent No. 6,730,293 ("293 patent") and claims 32, 33, and 40 in view of claims 106 and 116-121 of U.S. Patent No. 6,593,292 ("292 patent").

Applicants respectfully note that an essential inquiry in the double patenting analysis is the determination of "differences between the scope and content of the patent claim and the prior art." See MPEP § 804II.B.1. Here, the Examiner has failed to note the most crucial difference between the claims of the '293 and '292 patents and the pending claims. The pending claims are directed to a composition in which the biologically active agent and transporter are *non-covalently* bound whereas the claims of the '293 and '292 patents encompass *conjugates* in which the biologically active agent and transporter are *covalently* bound.

Applicants respectfully submit that one skilled in the art would have no reason to conclude that a complex having a non-covalently bound biologically active agent and transporter would be obvious in light of a conjugate having a biologically active agent covalently bound to a transporter. Therefore, Applicants respectfully request that the Examiner set forth reasons as to why the skilled artisan would make such a conclusion or withdraw the rejection.

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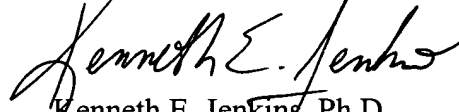
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,


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